AUG 3 0 2000

APPLIED IMAGING

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K001420.

Submitter Information (21 CFR 807.92(a)(1))

Submitter: Applied Imaging, Inc.
2380 Walsh Avenue, Building B
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phone: (408) 562-0250
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Contact: Diane Oates
Director, Quality Assurance
Applied Imaging, Inc.
phone: (408) 450-4304

Summary Date: May 5, 2000

Name of Device and Classification (21 CFR 807.92(a)(2))

Name (trade): SlideScan™

Name (usual): automated cell-locating device

Classification: 21 CFR 864.5260, Class II, JOY (81)

Identification of Legally Marketed Predicate Device(s) (21 CFR 807.92 (a)(3))

SlideScan is substantially equivalent to the Automated Cellular Imaging System (ACIS, ChromaVision Medical Systems, Inc., San Juan Capistrano, CA), cleared under premarket notification K984188.

SlideScan is identical or similar to its predicate in terms of: intended use, method of cell detection, device components, risk to the patient, and clinical performance.

2380 Walsh Avenue, Bldg. B, Santa Clara, California 95051 Telephone (408) 562-0250, Fax (408) 562-0264

Description of Device (21 CFR 807.92 (a)(4))

SlideScan is an automated, intelligent microscope and imaging system (cell-locating device). The system detects cells (objects) of interest by color and pattern recognition techniques, and it consists of: a microscope, keyboard, installed software, color monitor, "joystick," and printer. The SlideScan device is operated by healthcare professionals for interpretation and diagnosis.

The SlideScan displays images of cells on a monitor. It is the user's responsibility to classify the types of cells. Automatic relocation, capture and archiving of the cell images are performed by the instrument based upon operator selection. The instrument also can be used in the manual mode to systematically scan a slide and examine each field.

SlideScan records the cell locations and electronically stores the images, noting optical density, shape, measurements, instrument settings. Identification parameters include light adsorption, size, shape and the presence of a nucleus.

On user demand, SlideScan presents the nucleated cells for review and identification on a monitor. For visual identification and classification, the operator may also review the nucleated cells directly through the microscope ocular. SlideScan can relocate a cell on a slide using the stored location parameters for visual operator identification and verification, even after slide removal and replacement at a later time.

Intended Use (21 CFR 807.92 (a)(5))

SlideScan™ is an automated scanning microscope and image analysis system. It is intended for *in vitro* diagnostic use as an aid to the pathologist in the detection, classification, and counting of cells of interest based on particular color, intensity, size, pattern, and shape.

This particular application is intended to detect epithelial cells positively stained by immunohistochemistry for the presence of cytokeratins in heparinized bone marrow samples.

Similarities to the Predicate(s) (21 CFR 807.92 (a)(6))

A summary table of the similarities and differences between SlideScan™ and the predicate device (ACIS) follows.

Comparison Table of Technological Characteristics: Applied Imaging's SlideScan™ and the ChromaVision ACIS

Device Name	SlideScan™ (new device)	ACIS (K984188)
Indications for use	Aid to the pathologist in the classification and counting of cells of interest based on particular color, size and shape.	Aid to the pathologist in the classification and counting of cells of interest based on particular color, size and shape.
Method of cell detection	Colorimetric pattern recognition by microscopic examination of prepared cells by size, shape, hue, and intensity as observed by an automated computer controlled microscope and/or by visual observation by a health care professional.	Colorimetric pattern recognition by microscopic examination of prepared cells by size, shape, hue, and intensity as observed by an automated computer controlled microscope and/or by visual observation by a health care professional.
Device Components	• Automated microscope • Video camera • PC with windows-based operating system • Keyboard and control panel (touchscreen?) • Color monitor for display of information • Color printer for reports • Dual Control Stick	• Automated microscope • Video camera • PC with windows-based operating system • Keyboard and control panel (touchscreen?) • Color monitor for display of information • Color printer for reports • Slide Rack
Light Sources	Halogen lamp	Halogen lamp
Microscope Objectives	10x, 20x, 40x	10x, 20x, 40x

Brief Discussion of Nonclinical and Clinical Data (21 CFR 807.92(b)(1,2))

SlideScan demonstrates excellent precision and accuracy, as verified via a series of clinical studies. SlideScan precision was confirmed via intra- and inter-instrument evaluations conducted in multiple "runs" over multiple days. The data demonstrated excellent precision, with percent coefficients of variation (%CVs) of 0% in virtually every run. SlideScan data were also compared to data from manual scans, and this showed that SlideScan collected the same tumor cells at the same coordinates as were designated by the manual method .

SlideScan accuracy was confirmed via studies with both spiked samples and clinical samples. The spiked study demonstrated that SlideScan collected at least as many tumor cells as the manual method, and there were no false positive interpretations. The clinical study demonstrated that use of SlideScan provided results at least equal to, and in many cases better than, the use of manual scanning alone.

Performance Data - Conclusions (21 CFR 807.92 (b)(3))

The SlideScan system has been shown to be substantially equivalent to the predicate device, and safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 3 0 2000

Ms. Diane C. Oates
Vice President, Regulatory Affairs
and Quality Systems
Applied Imaging
2380 Walsh Avenue, Bldg. B
Santa Clara, California 95051

Re: K001420
Trade Name: Applied Imaging SlideScan™
Regulatory Class: II
Product Code: JOY
Dated: August 7, 2000
Received: August 8, 2000

Dear Ms. Oates:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(K) Number (if known): K001420

Device Name: SlideScan™

Indications for Use:

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This particular application is intended to detect epithelial cells positively stained by immunohistochemistry for the presence of cytokeratins in heparinized bone marrow samples.

Peter E Maheni

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001420

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE AS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over –the-Counter Use ___
(Per 21 CFR 801.109)